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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/028,852 | 12/21/2001 | Sebastian Bohm | TGZ-001A | 3328 |
| 959 | 7590 | 04/21/2005 | EXAMINER | |
| LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109 | | | SINES, BRIAN J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1743 | |

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,852

Applicant(s)

BOHM ET AL.

Examiner

Brian J. Sines

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-58,60-97,99-122,124-150 and 197-222 is/are pending in the application.
- 4a) Of the above claim(s) 204-221 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,10-36,38,40-58,60-68,71-97,101-122,124-128,131-150,197-201 and 222 is/are rejected.
- 7) ☒ Claim(s) 8,9,37,39,69,70,99,100,129,130,202 and 203 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

57

Art Unit: 1743

DETAILED ACTION

Election/Restrictions

Newly submitted claims 204 – 221 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The microfluidic apparatus, as recited in claim 1, does not require the incorporation or use of neither a droplet generating system, as recited in claim 204, nor an ejector, as recited in claim 220. Since the applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 204 – 221 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

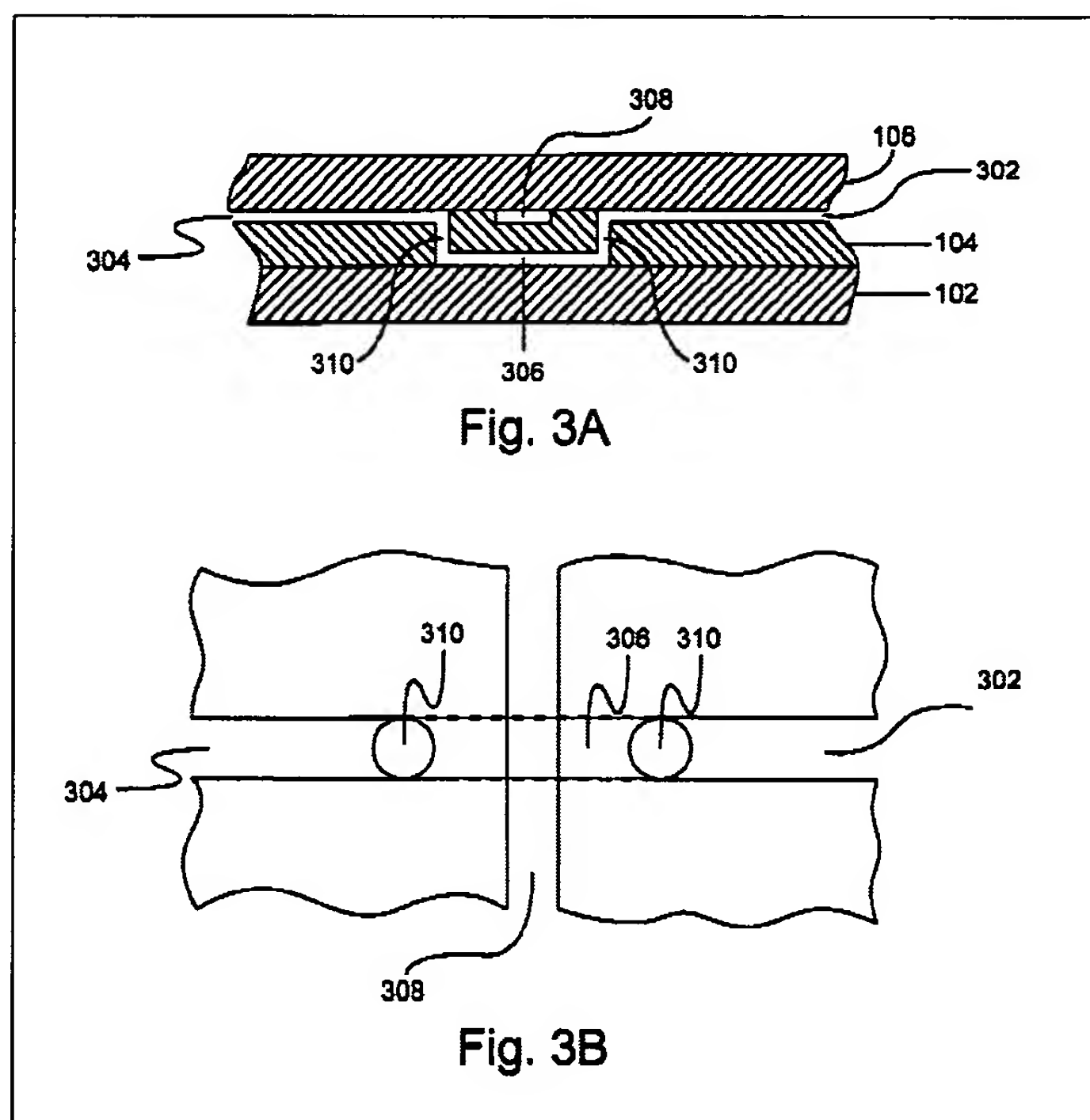
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. Claims 1, 7, 16 – 19, 24, 29 – 31, 39, 40, 45, 46, 47, 48, 53, 58, 60, 61 – 63, 68, 77, 78, 80, 90 – 93, 101, 102, 107, 108, 110, 120, 128, 131, 132, 137, 139, 149, 201 & 222 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow (U.S Pat. No. 6,494,230 B2).

Regarding claims 1, 19, 24, 29 – 31, 40, 48, 53, 58, 60, 61 – 63, 80, 90, 91 – 93, 101, 102, 110, 120, 139, 201 & 222, Chow anticipates the microfluidic apparatus structure

Art Unit: 1743

comprising: a microchannel (channel 306); and a fluid interface port (e.g., the opening into passage 310) (see figures 3A & 3B). As shown in figure 3B, the diameter of port 310 coincides with the diameter or width of the channel 306. Chow teaches that the dimensions of the microfluidic channel system structure is between $0.1\text{ }\mu\text{m}$ to about $500\text{ }\mu\text{m}$ (see col. 3, lines 38 – 67).



Regarding claims 7, 68, 90, 128, 201 & 222, as shown in figure 3A, Chow anticipates the incorporation of a covering layer (e.g. substrate 106).

Regarding claims 16, 39, 45, 77, 101, 102, 107, 131, 132 & 149, Chow anticipates the incorporation of a plurality of ports (310) (e.g., the opening on the left side of the apparatus leading from channel 304) (see figure 3A).

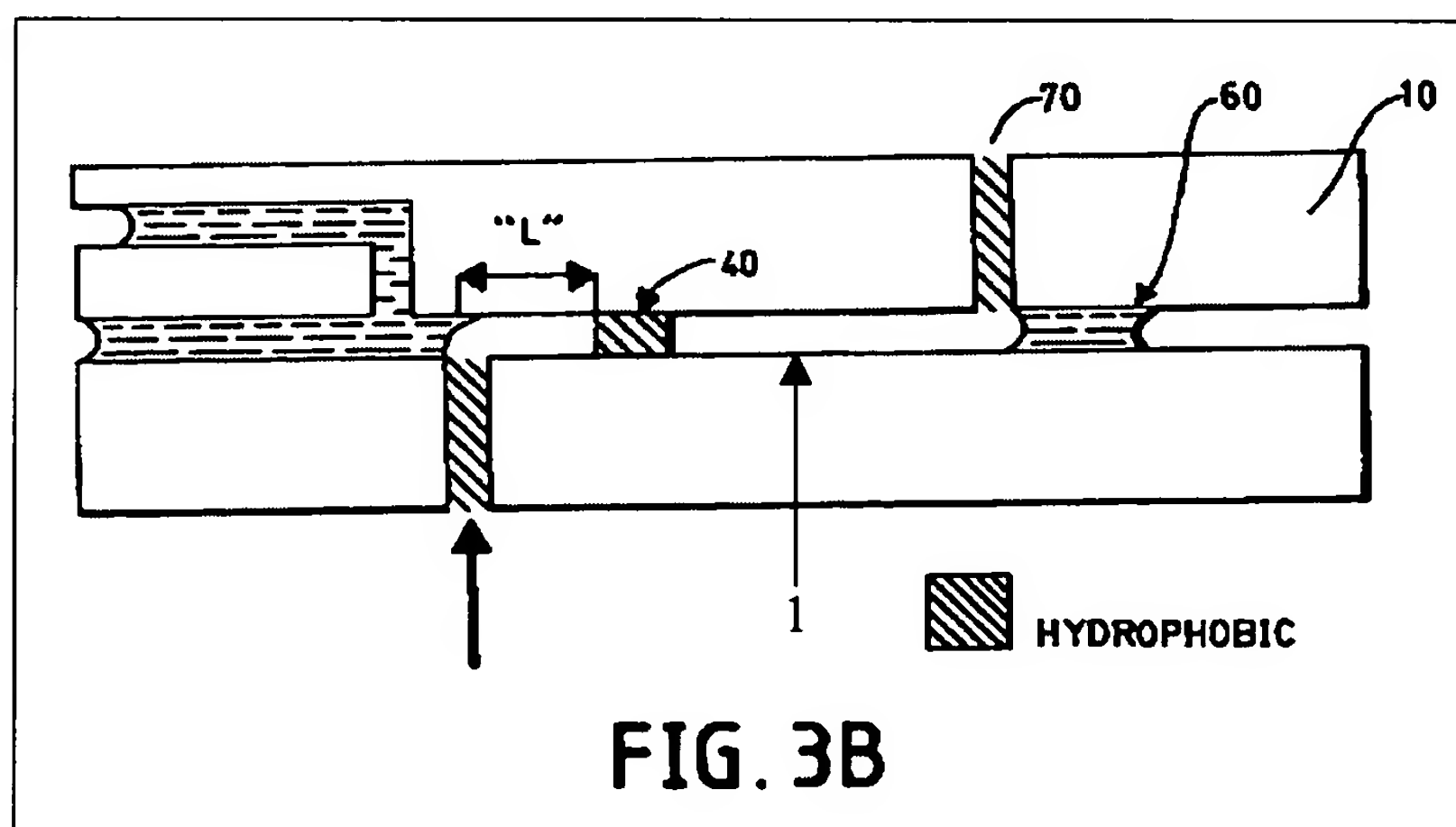
Art Unit: 1743

Regarding claims 17, 46, 78, 108 & 137, the port 310 has a circular or cylindrical shape (see figure 3B).

Regarding claims 18, 47, 79, 109 & 138, the recitation that the channel comprises a fluid is considered a process or intended use limitation.

2. Claims 1, 3 – 6, 10 – 13, 16, 18, 19, 22 – 24, 27 – 35, 39, 40 – 42, 45, 48, 51 – 53, 56 – 58, 60, 61 – 63, 71 – 74, 77, 80, 88, 89, 120, 131, 132, 139, 142, 143, 147 – 149 & 197 – 200 are rejected under 35 U.S.C. 102(e) as being anticipated by Handique et al. (U.S Pat. No. 6,130,098 A) (hereinafter “Handique”).

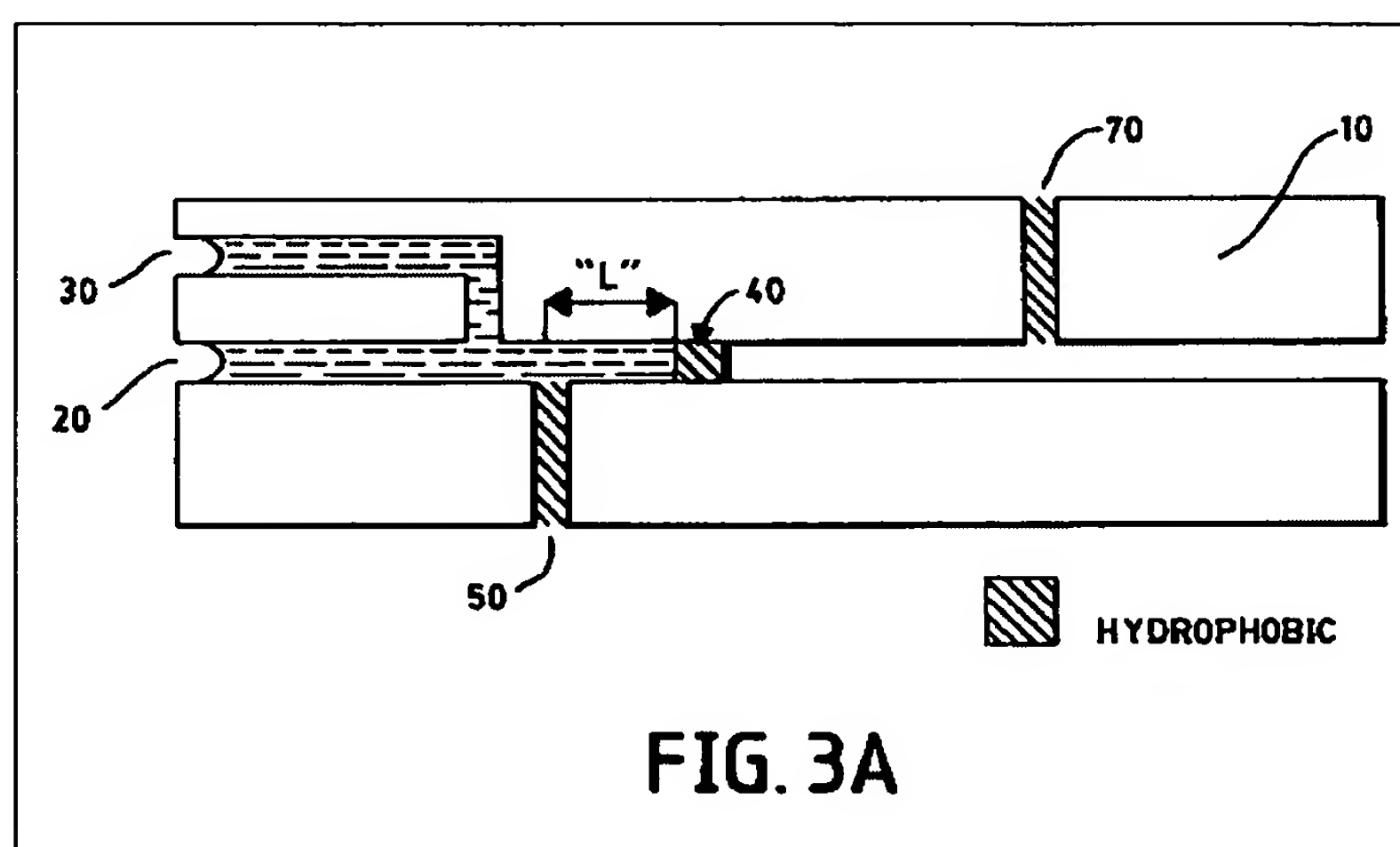
Regarding claims 1, 19, 24, 29 – 31, 40, 48, 53, 58, 60, 61 – 67, 80, 120, 139, 197 & 199, Handique anticipates the microfluidic apparatus structure comprising: a microchannel (labeled 1); and a fluid interface port (e.g., the opening corresponding to vent 70) (see figure 3B). As shown in figure 3B, the diameter of port 70 coincides with the diameter or width of the channel (1). Handique anticipates that the dimensions (e.g., channel width) of the microfluidic channel system structure is between 20 μm and 1,000 μm (see col. 7, lines 53 – 63).



Art Unit: 1743

Regarding claims 3 – 6, 22, 23, 32 – 35, 51, 52, 64 – 67, 83, 84, 142, 143 & 197 – 200, Handique anticipates the incorporation of hydrophilic and hydrophobic surfaces within the disclosed microfluidic apparatus for facilitating fluid flow control (see col. 14, lines 17 – 23).

Regarding claims 10, 11, 39, 71, 72, 131, 132, 149, Handique anticipates the incorporation of a second fluid interface port (e.g., 50) positioned on a side wall of the microchannel (see figure 3B).



Regarding claims 12, 27, 28, 41, 56, 57, 73, 74, 88, 89, 133, 147 & 148, Handique anticipates a droplet generating system (see col. 13, line 60 – col. 16, line 61).

Regarding claims 13, 42 & 134, Handique anticipates a droplet carrying element (e.g., this recitation can include any structure within the apparatus, such as a patterned surface or a channel sidewall, which contacts the sample fluid droplet).

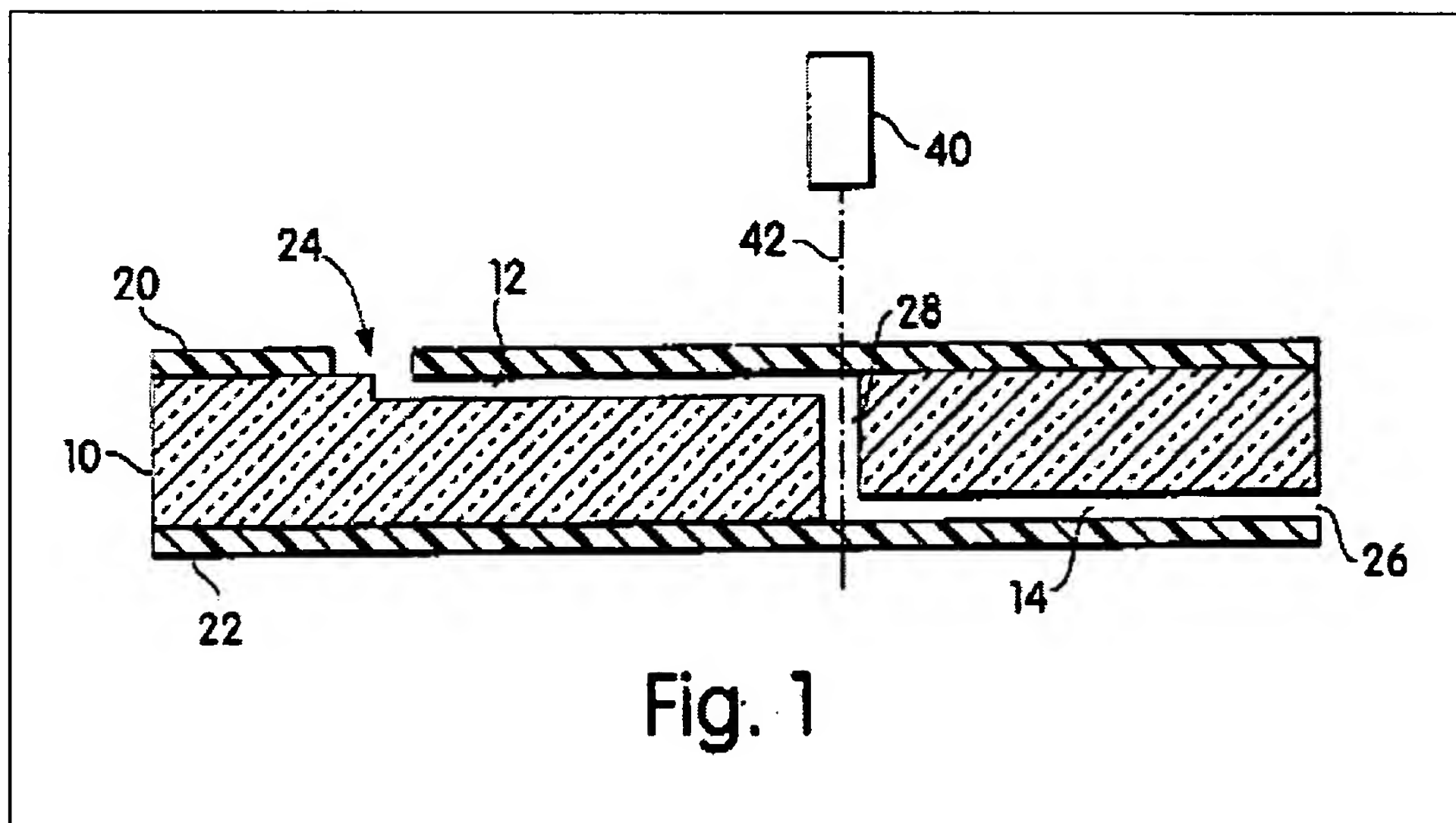
Regarding claims 16, 45, 77 & 149, Handique anticipates the incorporation of a plurality of ports (20 & 30) within the apparatus (see figure 3A).

Regarding claim 18, the recitation that the channel comprises a fluid is considered a process or intended use limitation.

Art Unit: 1743

3. Claims 1, 7, 15, 16, 18, 19, 24 – 26, 29 – 31, 36, 39, 40, 44, 45, 48, 53 – 55, 58, 60, 61 – 63, 68, 76, 80, 85 – 87, 90 – 93, 106, 107, 115 – 117, 120 – 122, 128, 131, 132, 136, 139, 144 – 146, 149, 150, 201 & 222 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuchs et al. (U.S Pat. No. 5,757,482 A) (hereinafter “Fuchs”).

Regarding claims 1, 19, 24 – 26, 29 – 31, 40, 48, 58, 60, 61 – 63, 80, 85, 90 – 93, 115 – 117, 120, 121, 139, 144, 201 & 222, Fuchs anticipates the microfluidic apparatus structure comprising: a microchannel (channel 12); and a fluid interface port (24)) (see figure 1). As shown in figure 1, the diameter of port 24 approximately coincides with the diameter or width of the channel 12. Fuchs teaches that the dimensions of the microfluidic channel system structure are between 10 μm to about 1,000 μm (see col. 5, lines 21 – 28).



Regarding claims 7, 25, 26, 36, 54, 68, 86, 87, 128, 145, 146, 201 & 222, Fuchs anticipates the incorporation of a covering layer (e.g., 20) (see col. 6, lines 13 – 52).

Regarding claims 15, 44, 76, 106 & 120 – 122, Fuchs anticipates the utilization of an optical detector (40) (see col. 6, lines 38 – 51).

Fig. 4

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

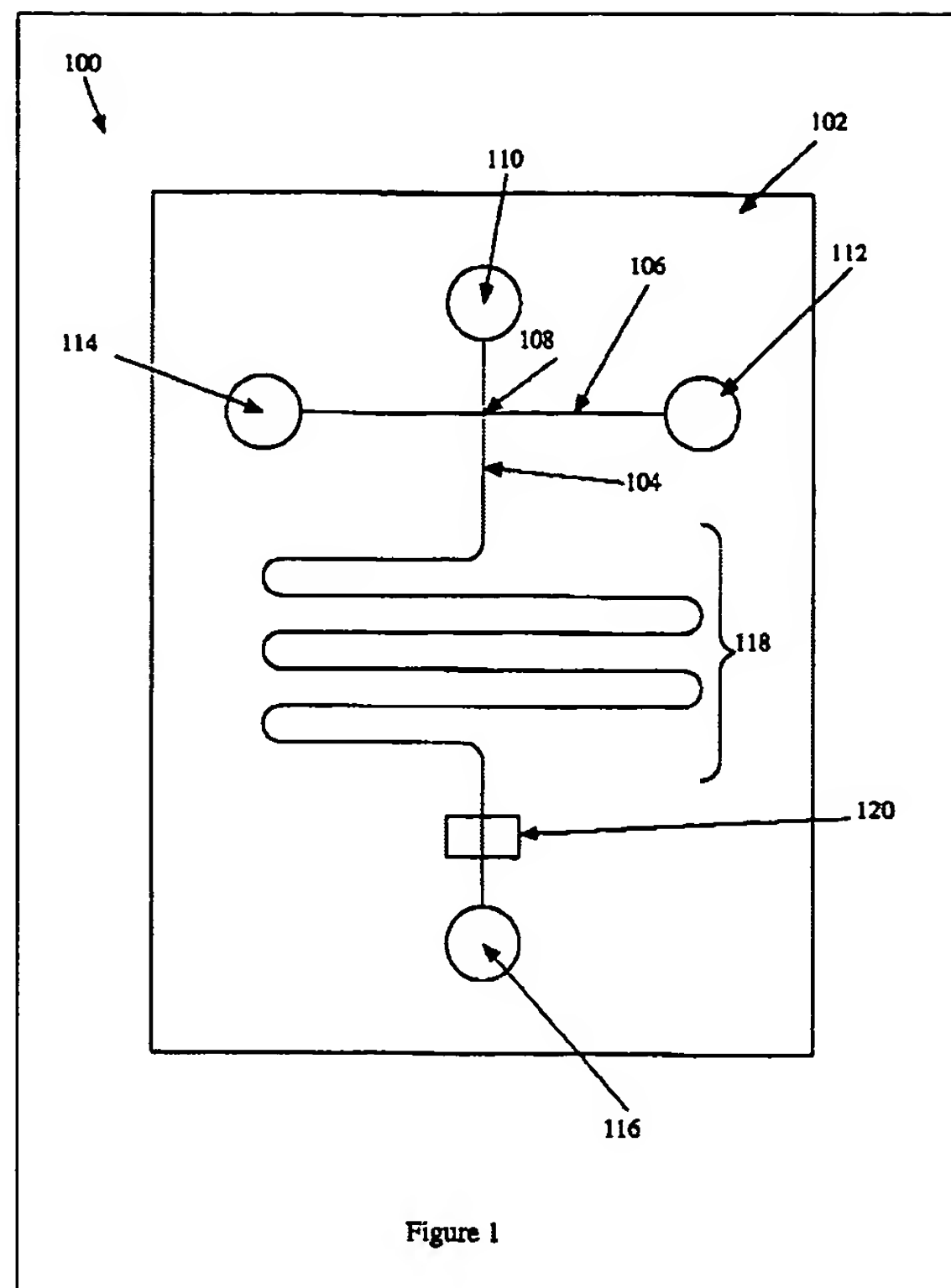
1. Claims 3 – 6, 22, 23, 32 – 35, 51, 52, 64 – 67, 83, 84, 94 – 97, 113, 114, 124 – 127, 142 & 143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow in view of Burns et al. (U.S. Pat. No. 6,057,149 A) (hereinafter “Burns”). Chow does not specifically teach the incorporation of hydrophilic and hydrophobic surfaces within microfluidic devices. However, as evidenced by Burns, for example, the incorporation of hydrophilic and hydrophobic surfaces within microfluidic devices for facilitating fluid flow control are well known in the art (see col. 15, lines 34 – 51). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate hydrophilic and hydrophobic surfaces within microfluidic devices for facilitating effective fluid flow control within the microfluidic apparatus.

2. Claims 3 – 6, 22, 23, 32 – 35, 51, 52, 64 – 67, 83, 84, 94 – 97, 113, 114, 124 – 127, 142 & 143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs in view of Burns

Art Unit: 1743

et al. (U.S. Pat. No. 6,057,149 A) (hereinafter “Burns”). Fuchs does not specifically teach the incorporation of hydrophilic and hydrophobic surfaces within microfluidic devices. However, as evidenced by Burns, for example, the incorporation of hydrophilic and hydrophobic surfaces within microfluidic devices for facilitating fluid flow control are well known in the art (see col. 15, lines 34 – 51). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate hydrophilic and hydrophobic surfaces within microfluidic devices for facilitating effective fluid flow control within the microfluidic apparatus.

3. Claims 20, 21, 49, 50, 81, 82, 111, 112, 140 & 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow in view of Kopf-Sill et al. (U.S. Pat. No. 5,842,787 A) (hereinafter “Kopf-Sill”). Chow does not specifically teach the use of non-linear channel system configurations within the disclosed microfluidic apparatus. Kopf-Sill does indicate that the disclosed apparatus, which utilizes a non-linear channel structure, is utilized in separations (see, e.g., col. 6, lines 7 – 26). Kopf-Sill does teach the incorporation of channels having curves or turns (e.g., serpentine portion 118) increases separation efficiency within microfluidic devices (see col. 1, lines 20 – 46; col. 5, lines 39 – 64; figure 1). Hence, a person of ordinary skill in the art would have had a reasonable expectation for success of utilizing a non-linear channel configuration within a microfluidic device to facilitate effective and efficient separations. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a non-linear channel system within the disclosed microfluidic apparatus.



4. Claims 12 – 14, 41 – 43, 73 – 75, 103 – 105, 118, 119 & 133 – 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow in view of Kercso et al. (U.S. Pat. No. 6,132,685 A) (hereinafter “Kercso”). Chow does not specifically teach the incorporation of a droplet generating system comprising either a pin feature or an ejector apparatus. Although Chow does indicate that the ports of the disclosed apparatus provide access for fluid material transport systems (see col. 7, lines 53 – 64). Kercso does teach the utilization of piezoelectric dispensing and pin transfer of small droplets of sample fluid, which is well known in the microfluidics art. Hence, as evidenced by Kercso, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in utilizing the recited features for facilitating effective transfer of fluid materials with microfluidic systems. The Courts have held

Art Unit: 1743

that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a droplet generating system within a microfluidics system in order to provide for more efficient and effective sample fluid transfer.

5. Claims 12 – 14, 41 – 43, 73 – 75 & 133 – 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handique in view of Kercso et al. (U.S. Pat. No. 6,132,685 A) (hereinafter “Kercso”). Handique does not specifically teach the incorporation of a droplet generating system comprising either a pin feature or an ejector apparatus. Although Handique does indicate the incorporation of a droplet generating system (see col. 13, line 60 – col. 16, line 61). Kercso does teach the utilization of piezoelectric dispensing and pin transfer of small droplets of sample fluid, which is well known in the microfluidics art. Hence, as evidenced by Kercso, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in utilizing the recited features for facilitating effective transfer of fluid materials with microfluidic systems. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a droplet generating system within a microfluidics system in order to provide for more efficient and effective sample fluid transfer.

6. Claims 12 – 14, 41 – 43, 73 – 75, 103 – 105, 118, 119 & 133 – 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs in view of Kercso et al. (U.S. Pat. No.

Art Unit: 1743

6,132,685 A) (hereinafter “Kercso”). Fuchs does not specifically teach the incorporation of a droplet generating system comprising either a pin feature or an ejector apparatus. Although Fuchs does teach that the introduction of sample fluid may be introduced various known fluid introduction systems (see col. 9, lines 41 – 47). Kercso does teach the utilization of piezoelectric dispensing and pin transfer of small droplets of sample fluid, which is well known in the microfluidics art. Hence, as evidenced by Kercso, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in utilizing the recited features for facilitating effective transfer of fluid materials with microfluidic systems. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a droplet generating system within a microfluidics system in order to provide for more efficient and effective sample fluid transfer.

Allowable Subject Matter

The indicated allowability of the pending claims in the office action mailed 10/19/2005 has been withdrawn in consideration of an updated prior art search and further review. Regarding the previously applied Chow reference, the applicant is directed to the additional structural embodiment shown in figures 3A and 3B. Rejections based on additional cited reference(s) are applied.

Claims 8, 9, 37, 39, 69, 70, 99, 100, 129, 130, 202 & 203 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1743

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 8, 37, 69, 129 & 202, the cited prior art neither teach nor fairly suggest the further incorporation within the devices of either Chow, Handique or Fuchs, the inclusion of a covering layer comprising an immiscible covering fluid.

Conclusion

The prior art made of record on form PTO-892 and not relied upon is considered pertinent to applicant's disclosure. The applicant is required under 37 C.F.R. § 1.111(c) to consider these references fully when responding to this office action (see MPEP § 714.02). Mehta et al. teach a microfluidic apparatus comprising sample wells being overlaid with mineral oil to prevent sample evaporation during processing (see col. 27, lines 26 – 41).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

